AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

1-23. (Canceled)

24. (New) A freeze-dried formulation consisting essentially of:

a follicle-stimulating hormone or a variant thereof;

a luteinising hormone or a variant thereof;

at least one surfactant selected from the group consisting of polyoxyethylene (20) sorbitan monolaurate, polyoxyethylene (20) sorbitan monopalmitate, and polyoxyethylene (20) sorbitan monooleate;

a stabilizer and tonicity agent selected from the group consisting of monosaccharides, disaccharides and sugar alcohols;

an antioxidant; and

a phosphate buffer.

25. (New) The freeze-dried formulation according to claim 24, wherein the follicle-stimulating hormone is a human follicle-stimulating hormone and/or the luteinising hormone is a human luteinising hormone.

26. (New) The freeze-dried formulation according to claim 25, wherein the follicle-stimulating hormone is a urinary human follicle-stimulating hormone and/or the luteinising hormone is a urinary human luteinising hormone.

27. (New) The freeze-dried formulation according to claim 24, wherein the follicle-stimulating hormone is a recombinant human follicle-stimulating hormone and/or the luteinising hormone is a recombinant human luteinising hormone.

28. (New) The freeze-dried formulation according to claim 24, wherein the follicle-stimulating hormone is present at a concentration (w/w) of 0.1 to 10 μg/mg of the total formulation.

29. (New) The freeze-dried formulation according to claim 28, wherein the follicle-stimulating hormone is present at a concentration of 0.3 to 5 μg/mg of the total formulation.

30. (New) The freeze-dried formulation according to claim 29, wherein the follicle-stimulating hormone is present at a concentration of 0.37 to 2 μg/mg of the total formulation.

31. (New) The freeze-dried formulation according to claim 24, wherein the luteinising hormone is present at a concentration of 0.1 to 3 μg/mg of the total formulation.

32. (New) The freeze-dried formulation according to claim 31, wherein the luteinising hormone is present at a concentration of 0.1 to 1 μg/mg of the total formulation.

33. (New) The freeze-dried formulation according to claim 32, wherein the luteinising hormone is present at a concentration of 0.1 to 0.6 μg/mg of the total formulation.

34. (New) The freeze-dried formulation according to claim 24, wherein the ratio of the number of International Units of follicle-stimulating hormone to luteinising hormone is within the range of 6:1 to 1:6.

35. (New) The freeze-dried formulation according to claim 34, wherein the ratio of the number of International Units of follicle-stimulating hormone to luteinising hormone is within the range of 4:1 to 1:2.

36. (New) The freeze-dried formulation according to claim 35, wherein the ratio of the number of International Units of follicle-stimulating hormone to luteinising hormone is within the range of 3:1 to 1:1.

37. (New) The freeze-dried formulation according to claim 36, wherein the ratio of the number of International Units of follicle-stimulating hormone to luteinising hormone is within the range of 2:1 and 1:1.

38. (New) The freeze-dried formulation according to claim 24, wherein the surfactant is polyoxyethylene (20) sorbitan monolaurate.

39. (New) The freeze-dried formulation according to claim 24, wherein the stabilizer and tonicity agent is sucrose.

40. (New) The freeze-dried formulation according to claim 39, wherein the surfactant is polyoxyethylene (20) sorbitan monolaurate.

41. (New) The freeze-dried formulation according to claim 40, wherein the follicle-stimulating hormone is a recombinant human follicle-stimulating hormone and/or the luteinising hormone is a recombinant human luteinising hormone.

42. (New) The freeze-dried formulation according to claim 41, wherein the antioxidant is methionine.

43. (New) The freeze-dried formulation according to claim 42 comprising: 0.1-10 μg/mg recombinant human follicle-stimulating hormone, 0.1-3 μg/mg recombinant human

luteinising hormone, and 0.001-0.1 mg/mg polyoxyethylene (20) sorbitan monolaurate, based on the weight of the formulation.

44. (New) The freeze-dried formulation according to claim 43 in which the relative weight amounts of the components comprise 12.0 μg of recombinant human follicle-stimulating hormone, 3.7 μg of recombinant human luteinising hormone, 30.0 mg of sucrose, 0.05 mg of polyoxyethylene (20) sorbitan monolaurate and 0.1 mg of methionine.

45. (New) The freeze-dried formulation according to claim 44 in which the relative weight amounts of phosphate buffer comprise 0.45 mg of $NaH_2PO_4xH_20$ and 1.11 mg of $Na_2HPO_4xH_20$.

46. (New) The freeze-dried formulation of claim 24 consisting of a follicle-stimulating hormone or a variant thereof, a luteinising hormone or a variant thereof, at least one surfactant selected from the group consisting of polyoxyethylene (20) sorbitan monolaurate, polyoxyethylene (20) sorbitan monopalmitate, and polyoxyethylene (20) sorbitan monooleate, a stabilizer and tonicity agent selected from the group consisting of monosaccharides, disaccharides and sugar alcohols, an antioxidant, and a phosphate buffer.

47. (New) The freeze-dried formulation of claim 46 consisting of recombinant human follicle-stimulating hormone, recombinant human luteinising hormone, polyoxyethylene (20) sorbitan monolaurate, sucrose, methionine, and a phosphate-buffer.

48. (New) The freeze-dried formulation according to claim 47 including: 0.1-10 μg/mg recombinant human follicle-stimulating hormone, 0.1-3 μg/mg recombinant human luteinising hormone, and 0.001-0.1 mg/mg polyoxyethylene (20) sorbitan monolaurate, based on the weight of the formulation.

49. (New) The freeze-dried formulation according to claim 48 in which the relative weight amounts of the components comprise 12.0 μg of recombinant human follicle-stimulating hormone, 3.7 μg of recombinant human luteinising hormone, 30.0 mg of sucrose, 0.05 mg of polyoxyethylene (20) sorbitan monolaurate and 0.1 mg of methionine.

50. (New) An article of manufacture comprising:

a first container filled with a freeze-dried formulation according to claim 24; and

a second container that comprises a solvent for reconstitution.

51. (New) An article of manufacture according to claim 50,wherein the second container contains water for reconstitution.

52. (New) The article of manufacture according to claim 51, wherein the freeze-dried formulation contains recombinant human follicle-stimulating hormone, recombinant human luteinising hormone, sucrose, polyoxyethylene (20) sorbitan monolaurate and methionine.

53. (New) The article of manufacture according to claim 52, wherein the freeze-dried formulation contains 0.1-10 μg/mg recombinant human follicle-stimulating hormone, 0.1-3 μg/mg recombinant human luteinising hormone, and 0.001-0.1 mg/mg polyoxyethylene (20) sorbitan monolaurate.

54. (New) The article of manufacture according to claim 53, wherein the relative weight amounts of the components in the freeze-dried formulation comprise 12.0 μg of recombinant human follicle-stimulating hormone, 3.7 μg of recombinant human luteinising hormone, 30.0 mg of sucrose, 0.05 mg of polyoxyethylene (20) sorbitan monolaurate and 0.1 mg of methionine.

55. (New) A method for manufacturing a freeze-dried formulation according to claim 24, comprising:

forming a mixture consisting essentially of a follicle-stimulating hormone or a variant thereof, a luteinising hormone or a variant thereof, at least one surfactant selected from the group consisting of polyoxyethylene (20) sorbitan monolaurate, polyoxyethylene (20) sorbitan monopalmitate, and polyoxyethylene (20) sorbitan monooleate, a stabilizer and tonicity agent selected from the group consisting of monosaccharides, disaccharides and sugar alcohols, an antioxidant, and a phosphate buffer; and

subjecting the mixture to lyophilization.

56. (New) The method according to claim 55, wherein the mixture contains recombinant human follicle-stimulating hormone, recombinant human luteinising hormone, sucrose, polyoxyethylene (20) sorbitan monolaurate and methionine.

57. (New) The method according to claim 56, wherein the mixture contains component amounts to yield a freeze-dried formulation containing 0.1-10 μg/mg recombinant human follicle-stimulating hormone, 0.1-3 μg/mg recombinant human luteinising hormone, and 0.001-0.1 mg/mg polyoxyethylene (20) sorbitan monolaurate, based on the weight of the formulation.

58. (New) The method according to claim 57, wherein the mixture contains component amounts to yield relative weight amounts of the components in the freeze-dried formulation comprising 12.0 μg of recombinant human follicle-stimulating hormone, 3.7 μg of recombinant human luteinising hormone, 30.0 mg of sucrose, 0.05 mg of polyoxyethylene (20) sorbitan monolaurate and 0.1 mg of methionine.